

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION**

KAREN LEIGH HUBBARD and
MICHAEL L. HUBBARD,

Plaintiffs,

V.

Civil Action File No:
1:18-cv-05648-WMR

BAYER HEALTHCARE
PHARMACEUTICALS, INC. and
BAYER PHARMA AG,

Defendants.

ORDER

This matter is before the Court on Plaintiff’s Motion to Exclude Testimony of Drs. Barnhart and Crowther [Doc. 30], and Bayer HealthCare Pharmaceuticals Inc.’s and Bayer Pharma AG’s (collectively, “Bayer”) Motion for Summary Judgment [Doc. 32]¹. Bayer argues that Plaintiffs have failed to establish any evidence of proximate cause that could connect Plaintiff’s injury to Bayer’s alleged failure to

¹ This case was directly filed in the Southern District of Illinois, as part of the YAZ/Yasmin Multi-District Litigation, *In re: Yasmin and YAZ (Drospirenone) Marketing, Sales Practices and Products Liability Litigation*, MDL No. 2100. At the conclusion of the MDL proceedings, the case, which was originally designated as Case No. 3:14-cv-10017-DRH, was transferred to this Court pursuant to 28 U.S.C. § 1404(a).

warn about the risks of Beyaz, a birth control pill designed and marketed by Bayer. For the following reasons, Bayer's Motion for Summary Judgment [Doc. 32] is **GRANTED**, and Plaintiff's Motion to Exclude Testimony of Drs. Barnhart and Crowther [Doc. 30] is **DENIED AS MOOT**.

I. BACKGROUND

It has been well-known for decades that all estrogen-containing birth control pills increase the risk of venous thromboembolism ("VTE"). (Doc. 32-1, Rowley Depo. at p. 30). Plaintiff took Bayer's birth control pills Yasmin, YAZ, and Beyaz for more than ten years, without problems, before she suffered a VTE in October 2012. (Doc. 32-1, Rowley Depo. at p. 101). Each of these pills contains the progestin drospirenone, as well as estrogen. (Doc. 32-1, Rowley Depo. at pp. 72, 91). YAZ and Beyaz differ from Yasmin in that they contain a lower dose of estrogen and a different dosing regimen. Beyaz also contains folic acid, an added benefit for reproductive-aged women. (Doc. 32-1, Rowley Depo. at pp. 26-27, 78).

Dr. Lawrence Rowley wrote Plaintiff's last prescription for Beyaz in December 2011, four months before Bayer changed its warning label to reflect that pills containing drospirenone "may be associated with a higher risk of venous thromboembolism (VTE)" than certain other birth control pills. (Doc. 32-1, Rowley Depo. at pp. 100-101, 107; Doc. 34-5). Even before his prescription to Plaintiff,

however, Dr. Rowley knew such pills carried a potentially higher risk of VTE, based on studies published as early as 2009. The FDA also published updates throughout 2011 reporting on the potentially higher risk of VTE. (Doc. 32-1, Rowley Depo. at pp. 27-31, 78-79, 83, 91-93, 96-100, 112, 117). Dr. Rowley was still prescribing Beyaz when he was deposed in 2017, five years after Bayer's 2012 label change. (Doc. 32-1, Rowly Depo. at p. 16).

Plaintiffs filed this lawsuit against Bayer asserting that Plaintiff's VTE resulted from Bayer's failure to warn about the risk from Beyaz. Plaintiffs allege claims for strict liability, negligence, design defect, fraud, breach of warranty, compensatory and punitive damages, and loss of consortium. (Doc. 2). Plaintiffs concede that if their failure to warn claim fails, so do all of their other claims. (Doc. 55, Hearing Transcript at pp. 63-64).

II. LEGAL STANDARD

Under Rule 56 of the Federal Rules of Civil Procedure, "[t]he court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). The moving party bears the burden of showing the absence of a genuine issue of material fact, looking at the evidence in the light most favorable to the nonmovant. *Adickes v. S. H. Kress & Co.*, 398 U.S. 144, 157 (1970); *Celotex Corp.*

v. Catrett, 477 U.S. 317, 323 (1986) (“[A] party seeking summary judgment always bears the initial responsibility of informing the district court of the basis for its motion, and identifying those portions of [the record] ... which it believes demonstrate the absence of a genuine issue of material fact.”).

After a motion for summary judgment has been properly supported, the nonmovant must present affirmative evidence “from which a jury might return a verdict in his favor” and that demonstrates the presence of “a genuine issue of fact that requires a trial.” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 257 (1986). “If reasonable minds could differ on the inferences arising from undisputed facts, then a court should deny summary judgment.” *Miranda v. B & B Cash Grocery Store, Inc.*, 975 F.2d 1518, 1534 (11th Cir. 1992) (citing *Mercantile Bank & Trust Co. v. Fidelity & Deposit Co.*, 750 F.2d 838, 841 (11th Cir. 1985)).

III. DISCUSSION

To prove a products liability claim based on a failure to warn, Georgia law requires a plaintiff to show “that the defendant had a duty to warn, that the defendant breached that duty, and that the breach proximately caused the plaintiff’s injury.” *Dietz v. Smithkline Beecham Corp.*, 598 F.3d 812, 815 (11th Cir. 2010) (citing *Wheat v. Sofamor, S.N.C.*, 46 F. Supp. 2d 1351, 1362 (N.D. Ga. 1999)). Within the context of prescription drugs, however, Georgia employs the learned intermediary doctrine,

which alters the general rule imposing liability on a manufacturer for failing to warn an end user of the known risks of its products. *See id.* According to the learned intermediary doctrine,

the manufacturer of a prescription drug ... does not have a duty to warn the patient of the dangers involved with the product, but instead has a duty to warn the patient's doctor, who acts as a learned intermediary between the patient and the manufacturer. The rationale for the doctrine is that the treating physician is in a better position to warn the patient than the manufacturer, in that the decision to employ prescription medication involves professional assessment of medical risks in light of the physician's knowledge of a patient's particular need and susceptibilities.

Id. (quoting *McCombs v. Synthes (U.S.A.)*, 587 S.E.2d 594, 594 (Ga. 2003)).

Regardless whether Bayer's warning was adequate at the time of Plaintiff's prescription — an issue that the Court need not decide — Plaintiffs must offer proof of proximate cause. “If the warning is inadequate, or merely presumed to be, the plaintiff must demonstrate that the deficient warning proximately caused the alleged injury to prevail.” *Dietz*, 598 F.3d at 816 (applying Georgia law and citing *Wheat*, 46 F. Supp. 2d at 1363); *see Ellis v. C.R. Bard, Inc.*, 311 F.3d 1272, 1283, n.8 (11th Cir. 2002); *Powell v. Harsco Corp.*, 209 Ga. App. 348, 350 (1993) (declining to decide whether the warning was adequate as a matter of law “because the failure of the installer to follow or even to read the installation instructions from the sales literature renders all remaining factual issues immaterial”).

The critical question in the proximate cause analysis is whether a different warning, one containing the information that Plaintiffs say was missing at the time of Plaintiff's prescription, would have led Dr. Rowley to make a different prescribing decision, *i.e.*, a decision not to prescribe Beyaz. *See Dietz*, 598 F.3d at 816.

Without evidence that a different warning would have changed the prescribing decision, Plaintiff cannot show that her injury would have been avoided but for Bayer's alleged failure to warn. *See id.* ("Appellant cannot demonstrate that SBC's alleged failure to warn . . . caused Dietz to commit suicide. The doctor provided explicit, uncontroverted testimony that, even when provided with the most current research and FDA mandated warnings, he still would have prescribed Paxil for Dietz's depression."); *Porter v. Eli Lilly and Co.*, No. 1:06-cv-1297-JOF, 2008 WL 544739, at *12-13 (N.D. Ga. Feb. 25, 2008) ("There is no evidence in Dr. Wolfberg's deposition testimony that a different warning on Prozac would have impacted Dr. Wolfberg's decision to prescribe Prozac.... For this reason, the court finds that Plaintiff cannot establish proximate cause for her causes of action of negligence, negligence per se, and strict liability.") (citing *Powell*, 209 Ga. App at 350).

Pursuant to Georgia's learned intermediary doctrine, a doctor's testimony that he would have prescribed the medication even when provided with the most current

warnings “severs any potential chain of causation through which [Plaintiff] could seek relief.” *Dietz*, 598 F.3d at 816.²

Here, the undisputed facts show that no different warning would have changed the prescribing decision and avoided the injury. Specifically, the fact show that:

- Dr. Rowley has known since the 1970s that all birth control pills carry the risk of venous blood clots (Doc. 32-1, Rowley Depo. at p. 30);

² The rule that a plaintiff must show that a different warning would have changed the prescribing decision is widely recognized. *See, e.g., Lineberger v. Wyeth*, 72 Pa. D. & C.4th 35 (2005), *aff’d*, 894 A.2d 141 (Pa. Super. Ct. 2006) (“Without evidence that Dr. Lafferty would not have prescribed the diet drugs, Lineberger is unable to establish that Wyeth’s alleged failure to warn was the proximate cause of her injuries.”); *Wyeth-Ayerst Labs. Co. v. Medrano*, 28 S.W.3d 87, 95 (Tex. App. 2000) (“In order to prove causation, the plaintiff must show that a proper warning would have changed the decision of the intermediary to prescribe the product.”); *Odom v. G.D. Searle & Co.*, 979 F.2d 1001, 1003 (4th Cir. 1992) (applying South Carolina law) (“The sole issue in this case, therefore, is whether an adequate warning to Odom’s doctor about the risk of sterility would have deterred him from prescribing the IUD.”); *Thomas v. Hoffman-LaRoche, Inc.*, 949 F.2d 806, 812 (5th Cir. 1992) (“We, therefore, hold that, under Mississippi law, in a prescription drug failure to warn case, the plaintiff must establish that an adequate warning would have convinced the treating physician not to prescribe the product for the plaintiff.”); *Rhodes v. Bayer Healthcare Pharms., Inc.*, No. 10-1695, 2013 WL 1282450, *4 (W.D. La. March 28, 2013) (“Plaintiffs bear the burden to show that a proper warning would have changed the decision of [the prescriber].”); *Sauls v. Wyeth Pharms., Inc.*, 846 F. Supp. 2d 499, 502-503 (D.S.C. 2012) (“Numerous courts have concluded that a plaintiff fails to carry her burden in establishing proximate cause in the absence of any evidence demonstrating how an adequate warning would have altered a physician’s prescription decision.”).

- When he wrote Plaintiff's prescription in December 2011, Dr. Rowley knew that Beyaz may carry a higher risk. (Doc. 32-1, Rowley Depo. at pp. 91-93, 97, 112); and
- Dr. Rowley continued to prescribe Beyaz for years after Bayer changed its label in April 2012 to add the risk information that Plaintiffs say was missing at the time of the Plaintiff's prescription. (Doc. 32-1, Rowley Depo. at p. 16).

Furthermore, Dr. Rowley did not alert his patients to the April 2012 label change at the time, because "the relative risk that was discussed was actually very small[.]" (Doc. 32-1, Rowley Depo. at p. 117:11-12). He reasoned that, for women like Plaintiff, who had been taking a pill like Beyaz for more than a decade at the time of the label change, "the relative risk of trying to pull everybody back as soon as you hear a -- an alert was so small that it really just didn't justify it, in my mind." (Doc. 32-1, Rowley Depo. at p. 117:15-18).

Dr. Rowley's deposition testimony was unequivocal. He testified as follows:

Q. Is it fair to conclude that the benefits of Beyaz outweigh the risk in patients who have already been taking it for some time with no problems?

A. Yes.

(Doc. 32-1, Rowley Depo. at p. 117:19-24)

Q. Did you conclude in December of 2011 that -- when you wrote the prescription for Beyaz, that the benefits outweighed the risks --

A. Correct.

Q. -- for Mrs. Hubbard?

A. Yes.

Q. Do you believe today that your decision to prescribe Beyaz for Mrs. Hubbard was appropriate?

A. Yes.

(Rowley Depo. at p. 116:5-13)

Q. All right. Did you change your prescribing -- the way you prescribed birth control to patients --

Q. -- after April of 2012?

A. Me personally?

Q. Yes.

A. No.

Q. Did you change it after 2012?

A. No.

(Doc. 56-1, Rowley Depo. at pp. 133:17-134:6)

This evidence breaks any causal connection between Bayer's allegedly inadequate warning and Plaintiff's injury.

In the face of this undisputed evidence, the only testimony Plaintiffs offer to create a fact question on proximate cause relates to Dr. Rowley's counseling practices:

Q. Is the counseling you give to patients for Beyaz any different than the counseling you provide for other birth control pills?

A. Yes.

Q. How was that counseling different?

A. The present time if I prescribe Beyaz I do inform the patient that there is some concern that there may be a slightly higher risk of a DVT, of a clot in the leg associated with using that versus some other types of birth control pills.

Q. Do you recall how long you've been providing that extra information?

A. About four years, somewhere there. Four -- four years.

Q. Is that a guess, or do you have a reason why you're saying four years?

A. If I remember correctly, in about 2012 the FDA came out with a statement that there may be an increased risk associated with it. (Doc. 34-1, Rowley Depo. at p. 35:3-21)³

This testimony does not create a triable fact question. First, Dr. Rowley testified that he believed he counseled Plaintiff the same way when he saw her in December 2011. He said “there had been studies before which had also suggested that increased risk, which I think would have been shared with her prior to that, even.” (Doc. 56-1, Rowley Depo. at p. 113:2-5). Dr. Rowley further testified that the information from the various FDA safety updates about the increased risk from medicines like Beyaz “[were] no different to what had come out from previous studies . . . talking about there may be a slight increased risk, so it wasn’t like an absolute game changer[.]” (Doc. 32-1, Rowley Depo. at p. 112:16-24). Dr. Rowley testified further that he did not give his patients additional counseling after the 2012 FDA alert because the risk of adverse side effects from the medication was basically

³ Plaintiffs also point to the fact that, before Bayer’s label change in 2012, Dr. Rowley did not reach any conclusions about whether Beyaz actually had a higher risk than other pills. (See Doc. 34, Plaintiffs’ Response Brief at p. 2.) Presumably, Plaintiffs seek to suggest that *after* the label change, Dr. Rowley *did* reach that conclusion. However, he testified just the opposite. (See Doc. 34-1, Rowley Depo. at p. 133:7-15 (“Q. And so after April of 2012 and the FDA statement did the practice group reach any new conclusion about whether YAZ, Yasmin, Beyaz had a higher risk of causing a blood clot than other birth control pills? A. No. We didn’t make a conclusion again.”)). If anything, this testimony supports Bayer’s defense.

the same and that his patients had been informed of the risks. (Doc. 56-1, Rowley Depo. at p. 113-116).

Second, even assuming some discernible difference between the way Dr. Rowley counseled Plaintiff and the way he counsels Beyaz patients today, he testified that he did not change his prescribing practices following the label change, and that he continued to prescribe Beyaz. (Doc. 32-1, Rowley Depo. at p. 16:13-17, see also Doc. 56-1, Rowley Depo. at p. 133:17-134:6).

Evidence of a change in the doctor's counseling following a label change, without evidence that the new warning label would have led to a different prescribing decision, is immaterial. Such evidence, by itself, does not "discredit or call into question [the] treating physician's testimony or show in another manner that the failure to warn was the proximate cause of injury." *Porter*, 2008 WL 544739, at *12 (citation omitted). Evidence of changed counseling alone therefore does not create a dispute of fact "that might affect the outcome of the suit," and it cannot preclude summary judgment. *Anderson*, 477 U.S. at 248.

Plaintiffs attempt to muddy this distinction by arguing that Dr. Rowley prescribed Beyaz less often following Bayer's 2012 label change. But the record is clear that any decline in his prescriptions was not because he stopped recommending Beyaz to patients. It was because "the patients themselves decided not to be on those

prescriptions.” (Doc. 56-1, Rowley Dep. at p. 134:17-135:20). The record is also clear, however, that Plaintiff did not make such decisions on her own, and that she relied on her doctor’s recommendations. Plaintiff testified:

Q. Well, I’m trying to understand whether you rely entirely on your doctor when you decide to take a medication or if you do any of your own independent research or if you talk to your husband --

A. No.

Q. -- or anybody else.

A. Whatever the man said, I say.

Q. Whatever your doctor recommends you to take, that’s how you decide; is that right?

A. Yes. He always told me --

Q. And I’m asking just generally. Is that always true? When you decide to take a prescription medication, it’s because your doctor has recommended it?

A. Correct.

(Doc. 57-2, Karen Hubbard Depo. at p. 33:11-34:2.)

On these undisputed facts, Plaintiff cannot show that any alleged inadequacy in Bayer’s warning label for Beyaz was a proximate cause of her injury. Dr. Rowley’s decision to prescribe Beyaz was informed by his actual knowledge that Beyaz may carry a higher risk of blood clots than other birth control pills. He stood by that prescription — and continued to write other prescriptions for Beyaz — years later. The causal connection between Bayer’s alleged failure to warn and Plaintiff’s injury is broken. *See Dietz*, 598 F.3d at 815-816; *Ellis*, 311 F.3d at 1283, n.8; *Krasnopolsky v. Warner-Lambert Co.*, 799 F. Supp. 1342, 1347 (E.D.N.Y. 1992).

IV. CONCLUSION

Plaintiffs cannot establish a fact issue on proximate cause, a necessary element of all of their claims. Because of Plaintiffs' failure of proof on this, Bayer's Motion for Summary Judgment [Doc. 31] is **GRANTED** and Plaintiffs' claims are **DISMISSED WITH PREJUDICE**. Because the Court grants Bayer's motion for summary judgment, Plaintiffs' Motion to Exclude Testimony of Drs. Barnhart and Crowther [Doc. 30] is **DENIED AS MOOT**. The Clerk of Court is directed to terminate this case.

IT IS SO ORDERED, this 3rd day of July, 2019.



WILLIAM M. RAY, II
United States District Court Judge
Northern District of Georgia